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K010303

Artscan 200 "510(k) Summary"

May 15, 2001

Artscan Oy
Annankatu 31-33 C 40
Helsinki, FIN-00100
Finland
+358 9 6831 1222 (phone)
+358 9 6831 0221 (fax)
Mr. Raimo Vaintola, Managing Director

Trade Name: Artscan 200 Arthroscopic Cartilage Stiffness Tester
Common Name: Arthroscopic cartilage stiffness testing device
Classification Name: Unknown as this device has not been classified. A 513g is hereby requested.

Artscan Oy is unaware of any Predicate device or Substantial equivalence device being distributed for use in humans in the United States at the present time.

Description: The Artscan 200 Arthroscopic Cartilage Stiffness Tester is a non-significant risk device. The design of the instrument is based on 15 years of research work on cartilage diseases by a group of scientists at the University of Kuopio, Finland. It consists of the following components: (1) a LapTop PC with MS Windows™ NT 4.0 operating system; (2) Artscan 200 program version v.2.1; (3) Artscan 200 Power Unit; (4) two Artscan measurement sensors- a "Normal Tissue Probe" 300 micron high indenter sensor for cartilage > 1.5mm thick and a "Thin Tissue Probe" 100 micron high indenter sensor for cartilage >.5mm thick. The Artscan 200 is a portable system which allows for use in clinical, research and veterinary environments. The Artscan 200 instrument is CE marked for sale in the EC and protected by global patents.

Intended Use: The Artscan 200 Arthroscopic Cartilage Stiffness Tester is indicated for an arthroscopic *in vivo* point measurement of articular cartilage stiffness in humans. The instrument can be used arthroscopically or during "open" surgical procedures. The Artscan 200 device is useful in determining early cartilage softening, which cannot be measured quantitatively with conventional methods. The new Artscan 200 system can help (1) detect possible cartilage disorders as an early stage before visual changes take place; (2) measure the biodynamical properties of articular cartilage during routine arthroscopy; (3) follow cartilage alterations after medical or surgical treatments as well as after cartilage repair; (4) monitor the development of various joint diseases, for example osteoarthritis and chondromalacia.

The Artscan 200 measurement procedure is based on a patented test method. A measurement rod sensor, containing a special indenter, is placed gently against the cartilage surface and pressed against it with a constant 10N force for about one second. The pressing force is monitored on the upper scale of the computer screen. The value for cartilage stiffness is given on the lower scale in 100ths of a N. All measurement information is stored by the computer and can be analysed later. Since the actual test takes only a few seconds, the cartilage surface is affected by minimal mechanical stress.

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Technological Characteristics:

The Artscan 200 instrument uses the "constant deformation" principle, where a certain constant shape and size Indenter is pressed against the cartilage with a Rod (or Reference) force of 10 N. This 10 N force value is empirical, since cartilage stiffness typically varies between 1 –5 N. Using the Reference force ensures that the indentation is complete i.e. the Indenter is totally inside the tissue to be measured.

Inside the Artscan 200 Sensor there are 2 strain gauges both of which are connected to the Rod and to the Indenter. The strain gauges form a Wheatstone bridge type of electrical measurement system, which transfers the small mechanical bending of Rod and Indenter into an electrical signal. This signal is amplified, A/D-converted and sent in digital form to the serial input port of the Lap Top computer. The Artscan 200 Power Unit contains a medical standard transformer through which all parts of the system, including the Lap Top computer, are powered.

Each Artscan 200 Sensor is marked with a serial number and calibrated in the factory with accurate weighs between 1 - 12 N. The calibration curve is stored on to a floppy disc, which is delivered to the user together with the Sensor. When using a certain Sensor, the user always gives the serial number of the Sensor first to the computer. This ensures the right calibration data is used with the proper Sensor.

The Rod and Indenter are made out of AISI 304 and AISI 316 stainless steel. This material has been widely used for years in surgical instruments in contact with human patients. The entire Sensor including the connecting cable is sterilized by the user in an autoclave (270F for 30 minutes) before each operation.

The Artscan 200 system is designed to meet EN 60601-1, EN 60601-1-1, EN 60601-1-2 and EN 60601-1-4 standards. The Artscan 200 is CE-marked in class IIa: "devices in short contact - less than one hour - with the patient".

Non-clinical Performance Data:

Please refer to the Attachments & Appendices, Numbers K thru S.

Clinical Performance Data:

Please refer to the Attachments & Appendices, Numbers T thru W. Also refer to Numbers X thru Z for letters from the three most experienced European Artscan users.

Conclusions based on Technological Characteristics, Non-Clinical Performance Data and Clinical Performance Data;

The Artscan 200 arthroscopic cartilage stiffness testing device is a "non significant risk" device used by orthopaedic surgeons for early detection of cartilage softening in human and animal joints. The actual measurement is only a few seconds and thus the possibility of damaging the cartilage is minimal.

The measuring Sensor, which is in contact with the patient, has an inert stainless steel construction and it is sterilized by autoclaving before each operation by the user. All electronics are designed to meet EN 60601-1 standard containing only medical standard components and isolation.

The Artscan 200 system was introduced commercially 3 years ago in Europe, where it is marketed and sold at present. The company is working closely with The International Cartilage Repair Society (ICRS) who is recommending that a biomechanical cartilage measurement become part of a standard patient investigative protocol.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Artscan Medical Innovations
c/o Mr. Robert E. Anthony
REA Incorporated
4804 Pin Oak Road
Akron, Ohio 44333

Re: K010303
Trade/Device Name: Artscan 200 Arthroscopic Cartilage Stiffness Tester
Regulation Number: 888.1100
Regulatory Class: II
Product Code: NGR
Dated: May 15, 2001
Received: May 18, 2001

Dear Mr. Anthony:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Walker, MD

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010303

Device Name: Artscan 200 Arthroscopic Cartilage Stiffness Tester

Indications For Use:

The Artscan 200 Arthroscopic Cartilage Stiffness Tester is indicated for an arthroscopic *in vivo* point measurement of articular cartilage stiffness in humans.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010303

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)